



APR - 2 2009

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,510,106

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,510,106, which claims the veterinary biologic product FEL-O-FAX LvK/FIV vaccine, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,348 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,348 days.

The period of extension has been calculated using the United States Department of Agriculture's determination of the length of the regulatory review period published in the Federal Register of September 17, 2007 (72 Fed. Reg. 52847). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (0) + 1,348 \text{ days} \\ &= 1,348 \text{ days (3.7 years)}\end{aligned}$$

Since the regulatory review period began October 15, 1999, after the patent issued (April 23, 1996), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,510,106
Granted:	April 23, 1996

Original Expiration Date¹: January 4, 2011

Applicant: Janet K. Yamamoto et al.

Owner of Record: The Regents of the University of California

Title: Methods and Compositions for Vaccinating Against Feline Immunodeficiency Virus

Product Trade Name: FEL-O-FAX LvK/FIV vaccine

Term Extended: 1,348 days

Expiration Date of Extension: September 13, 2014

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Center for Veterinary Biologics
510 South 17th Street, Suite 104
Ames, IA 50010

RE: FEL-O-FAX LvK/FIV vaccine
Docket No.: APHIS-2007-0121

Attention: Dr. Richard Hill

¹Subject to the provisions of 35 U.S.C. § 41(b).